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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/764,691

01/26/2004

Gary L. Bowlin

49122-0142(297109)

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7590  
Beth E. Arnold  
Foley Hoag LLP  
155 Seaport Boulevard  
Boston, MA 02210-2600

11/02/2007 •

EXAMINER

SINGH, SATYENDRA K

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

11/02/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/764,691	Applicant(s) BOWLIN ET AL.	
	Examiner Satyendra K. Singh	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4, 5 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 3, 6-20 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicant's response and amendments to the claims filed with the office on August 27<sup>th</sup> 2007 is duly acknowledged.

Claims 3, 6-20 and 22 (groups II-VII) remain withdrawn from further consideration.

Claims 1, 4, 5, and 21 (group I; as currently amended) are pending and examined on their merits in this office action. Claim 2 has been canceled.

The following action contains new grounds of rejection necessitated by applicant's current amendments to the pending claims.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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1 Claims 1, 4, 5 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffee RA (WO 98/03267; IDS, citation # 70), Coffee RA (US 2001/0003148; IDS, citation # 1), and Coffee RA (US 6,252,129; IDS, citation No. 46).

Claims are directed to "Electrodeposited fibrin matrix with cells", wherein the cells are delivered to the matrix during fabrication of the electrodeposited fibrin matrix, wherein the cells are suspended in a solution comprising molecules capable of forming fibrin during delivery to the matrix, or wherein the cells are entrapped within the matrix during fabrication of the electrodeposited fibrin matrix, wherein the cells are suspended in a fibrinogen solution during delivery to the matrix (see instant claims 1, and 21).

*"[E]ven though **product-by-process** claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).*

Coffee RA (WO 98/03267, IDS) discloses electrohydrodynamically making (taken as a process of electrodeposition; see Coffee RA, pages 9-10, in particular) fiber mats for use in treating wounds or burns (see Coffee RA, abstract, and claims 1-5, in particular). Among the various fibers that may be used is fibrin, which may be formed *in situ* by action of thrombin on fibrinogen (see Coffee RA, page 28, claims 20, 25-26, 36). A wide range of biologically active ingredients may be incorporated, including nucleic acids, growth factors, therapeutic agents, cells, etc. (see Coffee RA, pages 5-6, in particular). The fiber mat may be incorporated into conventional bandages and wound dressings (see Coffee RA, pages 6 and 17, in particular), thus the product produced encompasses electrodeposited fibrin matrix with cells. In addition, Coffee RA discloses the fact that the liquid used for electrodeposition may "comprise a solution, suspension, microsuspension, emulsion....which may contain an active components or components (see Coffee RA, page 5, 2<sup>nd</sup> and 3<sup>rd</sup> paragraphs, pages 6-7, 22-23 and 28, in particular), which are disclosed as encompassing various pharmaceutical compounds such as

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drugs, including "biological products such as cells, and cytokines" (see page 5, 3<sup>rd</sup> paragraph, in particular), wherein the cells may be interspersed in or between layers of the electrodeposited composition (see page 23, 2<sup>nd</sup> paragraph, in particular).

Coffee RA (US 2001/0003148; IDS) discloses an electrohydrodynamic method of producing mats from suitable fibers, which process is reasonably expected to produce electrodeposited matrix with cells. Specifically, fibrin is produced (paragraph 0017, 0085, claim 26 and claim 36). The fibrin fibers may comprise additional biologically active material (paragraph 0021). Coffee RA (US 6,252,129) discloses an electrohydrodynamic method of producing mats from suitable fibers. Specifically, fibrin is produced (column 3, line 43; column 14, line 12). The fibers may comprise additional biologically active material (see, paragraph bridging columns 3-4).

Even though, an electrodeposited fibrin matrix comprising cells is not explicitly exemplified by the referenced inventions of Coffee RA (WO 98/03267; IDS, citation # 70), Coffee RA (US 2001/0003148; IDS, citation # 1), and Coffee RA (US 6,252,129; IDS, citation No. 46), this product is clearly envisioned by the reference disclosures.

Given the fact that Coffee RA (WO 98/03267, IDS) discloses that a product as claimed, i.e. an electrodeposited fibrin matrix is made using solutions or suspensions comprising fibrinogen and/or thrombin (see claims 15-20, 26, 36-38, in particular), wherein the solutions or liquids can be further added with polymers or cells and/or other biological components such as growth factors, drugs, peptides, etc (see Coffee RA, discussion above), and electrodeposited on a desired surface to produce a fibrin mat or web (i.e. fibrin matrix) which can be interspersed with the cells between the layers (see

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Coffee RA, page 23, 2<sup>nd</sup> paragraph, in particular), it would have been clearly obvious to a person of ordinary skill in the tissue engineering art to incorporate cells (such as skin cells) and/or other biological components (such as drugs, hormones, peptides, etc.) in the fibrin matrix in order to provide an electrodeposited fibrin matrix with cells having the benefits of incorporated biological agents such as drugs, for example in the form of a superior wound dressing or covering, or skin substitute, as exemplified by Coffee RA, WO 98/03267; see abstract, pages 4-7, pages 17-19, pages 22-23 and 28; and claims, in particular.

The process limitations as recited in instant claims, wherein the cells are delivered to the matrix during fabrication of the electrodeposited fibrin matrix, wherein the cells are suspended in a solution comprising molecules capable of forming fibrin during delivery to the matrix, or wherein the cells are entrapped within the matrix during fabrication of the electrodeposited fibrin matrix, wherein the cells are suspended in a fibrinogen solution during delivery to the matrix (see instant claims 1, and 21), are disclosed by Coffee RA, as it describes the same process steps of electrodeposition of materials in liquid, solution or suspension form (containing polymers, and/or cells and other beneficial biological components such as drugs, hormones, etc.) in order to obtain the electrodeposited fibrin matrix or mat containing cells. In the absence of any evidence to contrary, the "electrodeposited fibrin matrix with cells" product as explicitly suggested by the referenced invention of Coffee RA (WO 98/03267, US 2001/0003148), and US 6,252,129 is deemed to be substantially similar if not the same as the claimed product.

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Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the tissue engineering art at the time the claimed invention was made.

*As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).*

*As per MPEP 2144.06, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).*

*As per MPEP 2144.04, Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render prima facie obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.).*

### **Response to Arguments**

Applicant's arguments with respect to claims 1, 4, 5 and 21 (as they pertain to the prior art rejections of record) have been considered but are moot in view of the new ground(s) of rejection made in this office action.

### **Conclusion**

**NO claims are allowed.**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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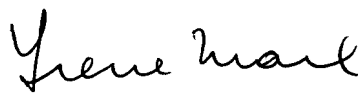
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Satyendra K. Singh  
Patent Examiner  
Art Unit 1657

  
**IRENE MARX**  
**PRIMARY EXAMINER**